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IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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QUESTIONS PRESENTED FOR REVIEW

1. Is the "reasonable anticipation" standard, rejected by this Court in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) as a "watered down and improper standard" under Section 32 of the Lanham Act, 15 U.S.C. §1114 for restraining sale of a generic drug in the accustomed appearance for the drug, the proper standard for restraining the same conduct under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a)?

2. Does the decision below improperly evade the Lanham Act legal standards for "functionality" and "secondary meaning", affirmed by this Court in *Inwood, supra*, by applying New Jersey state law to prohibit interstate commerce throughout the United States in a generic drug product lawfully manufactured in another state and lawfully approved in its publicly accustomed appearance by the United States Food and Drug Administration, thereby interfering with the drug substitution laws of the other states?

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED FOR REVIEW ..	i
TABLE OF AUTHORITIES	iv
OPINIONS BELOW	1
JURISDICTION	2
STATUTES INVOLVED	2
STATEMENT OF THE CASE	2
1. History Of The Drug Product In Suit	4
2. The Evidentiary Proceedings	7
REASONS FOR GRANTING THE WRIT:	
A. The Decision Below Conflicts With This Court's Decision In *Inwood* By Applying The "Watered Down And Incorrect" "Reasonable Anticipation" Standard To Prohibit Manufacture And Sale Of A Generic Drug Product In The Accustomed Appearance For The Drug	10
B. The Decision Below Conflicts With The Decisions Of This Court And The Second Circuit In *Inwood* As To The Standards For "Functionality" Of Drug Color ...	15
C. The Decision Below Conflicts With The Decisions Of This Court And The Second Circuit In *Inwood* As To The Standards For Establishing "Secondary Meaning" Of Drug Color	20

D. The Lower Courts Improperly Based A Nationwide Injunction On New Jersey State Law to Evade This Court's *Inwood* Decision 26

E. The Decision Below Granting Exclusive Trade Rights From Illegal Drug Sales And Promotion Is In Conflict With The Decisions Of This Court And The Other Circuits 28

CONCLUSION 30

APPENDIX (Separate Volume)

Opinion of the Third Circuit in *Ciba-Geigy Corporation v. Bolar Pharmaceutical Co., Inc.* .. 1-4

Preliminary Injunction Order against Petitioner, Bolar Pharmaceutical Co., Inc. entered October 4, 1982 5-7

Opinion of the District Court for the District of New Jersey in *Ciba-Geigy Corporation v. Bolar Pharmaceutical Co., Inc.*, 215 U.S.P.Q. 769 (1982) 8-50

Order of the District Court for the District of New Jersey Dismissing Counterclaims and Converting Preliminary Injunction Hearing to Final Trial on the Merits 51-53

Final Judgment and Order of the District Court for the District of New Jersey, entering Final Injunction against Petitioner, Bolar Pharmaceutical Co., Inc. 54-55

Section 43(a) of the Lanham Act, 15 U.S.C. Section 1125(a) 56

New Jersey Statutes Annotated Sections 56:4-1 and 56:8-2 57

Decision of the Second Circuit, on remand, following *Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) 58-60

TABLE OF AUTHORITIES

Cases

American Safety Table Company v. Schreiber, 269 F.2d 255 (2nd Cir. 1959) 16
Anti-Monopoly, Inc. v. General Mills Fun Group, Inc., 684 F.2d 1316 (9th Cir. 1982), *cert. denied*, ... U.S. ..... (1983) 24
Bayer v. United Drug, 272 F. 505 (S.D. N.Y. 1921) 22
Campbell v. Hussey, 368 U.S. 297, 301 (1961) . 27
Cameo, Inc. v. Plough, Inc., 185 U.S.P.Q. 228 (N.D. Ohio 1975) 29
Clairol Incorporated v. Holland Hall Products, Inc., 165 U.S.P.Q. 214 (TTAB 1970) 29
Cloverleaf Butter Co. v. Patterson, 315 U.S. 148 (1942) 27
Coca-Cola Co. v. Snow Crest Beverages, Inc., 64 F.Supp. 980 (D. Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947) . 16
Compco Corp. v. Day Brite Lighting, Inc., 376 U.S. 238 (1964) 27
DuPont Cellophane Co. v. Waxed Prods. Co., 85 F.2d 75 (2nd Cir. 1936) 23, 24
Famolare, Inc. v. Melville Corp., 472 F.Supp. 738 (D. Hawaii 1979), *aff'd*, 652 F.2d 62 (9th Cir. 1981) 17
Haughton Elevator Co. v. Seeberger, (Com. of Pat. 1950), 85 U.S.P.Q. 80 24
In re Stellar International Inc., 159 U.S.P.Q. 48 (TTAB 1968) 29
In re Taylor, 133 U.S.P.Q. 490 (TTAB 1962) .. 29
Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc., 456 U.S. 844 (1982) ..... *passim*

Ives Laboratories, Inc. v. Darby Drug Co., No. 80-7314 (July 7, 1982) 10
Kellogg Co. v. National Biscuit Co., 305 U.S. 111. (1938) ..... *passim*
King Seeley Thermos Co. v. Aladdin Industries, Inc., 321 F.2d 577 (2nd Cir. 1963) 24
Local 174, Teamsters Union v. Lucas Flour Co., 369 U.S. 95, 103 (1962) 27
Manhattan Medicine Co. v. Wood, 108 U.S. 218 (1882) 29
McDermott v. Wisconsin, 228 U.S. 115 (1913) . 27
Morton Salt Co. v. Suppinger, 314 U.S. 488 (1942) . 29
Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569 (2nd Cir. 1959), *cert. denied*, 362 U.S. 919 (1960) 16
Pagliero v. Wallace China Co., 198 F.2d 339 (9th Cir. 1952) 16
Pennsylvania R.R. v. The Public Service Commission, 250 U.S. 566, 568-569 (1919) 27
Roberts v. Ross, 344 F.2d 747, 751-752 (3rd Cir. 1965) 16
San Diego Building Trades Council v. Garmon, 359 U.S. 236, 242 (1959) 27
Scott v. Marcalus, 326 U.S. 249 (1945) 13, 14
Sears Roebuck & Co. v. Stiffel Company, 376 U.S. 225 (1964) 15, 27
Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169, 185 (1896) 14
SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1065 (1980) 4
Strey v. Devine's, Inc., 217 F.2d 187 (7th Cir. 1954) 29
United States v. Urbuteit, 335 U.S. 355 (1948) 29
U.S. v. Ciba-Geigy Corporation, 1976-1 Trade Cases ¶60,908 (D. N.J. 1980) 4

U.S. v. Generic Drug Corp., ... U.S. ..... (March 22, 1983) 5
Vibrant Sales, Inc. v. New Body Boutique, Inc., 652 F.2d 299 (2nd Cir. 1981) 16
West Point Manufacturing Co. v. Detroit Stamping Co., 222 F.2d 581 (6th Cir. 1955) 16
William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924) 16, 20
Worden v. California Fig Syrup Co., 187 U.S. 516 (1902) 29

Statutes

15 U.S.C. §§1064(c) and 1065(4) 15, 24
15 U.S.C. §1121 4
15 U.S.C. §1114, Lanham Act Section 32 ... 2, 11, 12, 13
15 U.S.C. §1125(a), Lanham Act Section 43(a) .. 2, 12, 13
21 U.S.C. §321(g)(2) 27
21 U.S.C. §§334 and 351 ..... 5, 28
21 U.S.C. §352 ..... 6, 28, 29
28 U.S.C. §§1331 and 1338 4
28 U.S.C. §§1254(1) and 2101(c) 2
New Jersey Statutes §56:4-1 and §56:8-2 2

Treatises

Abraham S. Greenberg, "Patent" Clauses of the Lanham Act, 38 Trademark Reporter, pp. 3-47, 19 (1948) 15
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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

OPINIONS BELOW

The opinion of the District Court for the District of New Jersey is reported at 215 U.S.P.Q. 769 (1982). It is reprinted in the Appendix at App. 8-50. The unreported preliminary injunction entered by the District Court on October 4, 1982 is reprinted in the Appendix at App. 5-7. The unreported decision of the Third Circuit Court of Appeals is reprinted in the Appendix at App. 1-4. The unreported orders of the District Court converting the preliminary injunction hearing to a final trial on the merits and entering a permanent injunction are reprinted in the Appendix at App. 51-55.

JURISDICTION

A writ of certiorari is sought to review the judgment of the United States Court of Appeals for the Third Circuit dated and entered October 14, 1983. The jurisdiction of this Court is invoked under 28 U.S.C. §§1254(1) and 2101(c).

STATUTES INVOLVED

The federal statutory provision involved is Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a). The state statutory provisions involved are New Jersey Statutes Annotated, Sections 56:4-1 and 56:8-2. These provisions are set forth in full in the Appendix at App. 56-57.

STATEMENT OF THE CASE

This is an action brought by Ciba-Geigy Corporation ("Ciba") against Bolar Pharmaceutical Co., Inc. ("Bolar"), Petitioner herein, under Sections 32 and 43(a) of the Lanham Act, and New Jersey state law, to restrain Bolar's manufacture in New York of a generic prescription drug in the same color capsules used by Ciba for the same drug. Full evidentiary hearings were held in April, May and June, 1982. Also in June, 1982, this Court unani-

mously decided *Inwood Laboratories, Inc. et al. v. Ives Laboratories, Inc.*, 456 U.S. 844 in favor of generic drug manufacture in publicly accustomed capsule colors.

Nevertheless, by opinion dated August 11, 1982, the trial court applied the "reasonable anticipation" standard specifically rejected by this Court in *Inwood*, to find Bolar guilty of "passing off" an "unprivileged imitation" under the Lanham Act and New Jersey state law, despite the fact that there was no illegal substitution or "passing off" of the Bolar product for the Ciba product. (App. 46). The trial court also specifically declined to follow the legal standards for "functionality" and "secondary meaning" of drug appearance affirmed by this Court in *Inwood*.[1]

On appeal, the Third Circuit summarily affirmed the trial court (App. 1-4). The Third Circuit recognized the conflict with this Court's *Inwood* decision, but held it was not required to address the issue of conflict with *Inwood* under the Lanham Act because the lower court's injunction could be based solely on New Jersey law:

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[1] The trial court acknowledged that use of accustomed colors "will facilitate generic substitution" (App. 18, 47) but "predicate[d]" its "rule of law upon an assumption that some pharmacists do and may illegally substitute generic drugs" (App. 32) and asserted that its "indictment could logically extend to any generic manufacturer who produced a look-alike drug" (App. 30). This was despite the rejection by this Court in *Inwood* of a rule of law based on the "assumption that a pharmacist . . . will be unable to resist the temptation to profit from illegal activity" (456 U.S. 844 at 856, footnote 17). In making this assumption, the trial court relied on a number of indictments of pharmacists in New York City for welfare fraud. The drugs involved were not the products in suit here; they included generic drugs available in different colors, so that the indictments are not probative of the drug appearance issue (DX 12A). Reliance on such indictments was criticized by this Court in *Inwood* (*Id.* at 857).

> However, we need not address this issue because the district court's conclusions regarding the New Jersey state law claims of "passing off" and "unprivileged imitation" are mandated by *SK&F* and provide a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief. (App. 4).

This was despite its earlier holding in *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1065 (1980) that the legal standards for New Jersey state law were the same as those for the Lanham Act.

The Third Circuit reliance on New Jersey state law is a transparent effort to evade *Inwood*. Bolar is a New York corporation which manufactured its generic product in New York and intentionally avoided selling its product into New Jersey. New Jersey has no interest in or subject matter jurisdiction over Bolar's interstate generic drug business outside of New Jersey.[2]

1. History of the Drug Products in Suit

Respondent Ciba is the U.S. arm of a major Swiss drug conglomerate, Ciba-Geigy A.G. Ciba has a prominent market position in antihypertensive (blood-pressure reducing) drugs. As a result of antitrust action brought by the Justice Department against Ciba, its patents covering the product in suit were dedicated to the public in 1981. *U.S. v. Ciba-Geigy Corporation*, 1976-1 Trade Cases ¶60,908 (D. N.J., 1980).

In August of 1976, Ciba's competitor Pfizer began to market Minipress (Prasosin), a new antihypertensive drug.

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[2] Ciba asserted jurisdiction under 15 U.S.C. §1121; 28 U.S.C. §§1331, 1338, and the doctrine of pendent jurisdiction. The lower courts have declined to consider Bolar's objection to subject matter jurisdiction under New Jersey state law.

The two principal dosages of Minipress were in pink/white and blue/white capsules [R. 60-61, 800-802, 1045, 1199; DX 57, 40, 13A, 13B, 1, 2]. Ciba was simultaneously attempting to launch a new antihypertensive named "Apresazide" containing two different chemical ingredients, in order to maintain its market share.

At the time Pfizer introduced Minipress, Ciba discovered that its first production batches of Apresazide were decomposed and adulterated by an unknown brown chemical reaction product. Rather than fall further behind Pfizer by developing a pure drug, Ciba deliberately shipped the decomposed and adulterated Apresazide into commerce in October, 1976 without first advising or seeking approval from the Food and Drug Administration for the contaminant as required by law, 21 U.S.C. §§334, 351 [R. 1381-1386; DX 81, 83, 84],[3] see *United States v. Generix Drug Corp.*, ... U.S. ..... (March 22, 1983).

Ciba's introduction of its adulterated Apresazide was two months after Minipress came on the market. The pink/white and blue/white capsule colors of the two principal dosage forms of Apresazide are identical to the corresponding colors of the Minipress capsules [PX 2, 3, DX 1, 2, 13A, 13B, 41; R. 800-802, 1047].

At the time Ciba introduced Apresazide, the prestigious National High Blood Pressure Education Program Task Force had divided proper hypertension therapy into a sequence of four drug treatment steps, steps 1-4. Accord-

[3] Record references are to the numbered pages of the Record on Appeal, and include documentary exhibits. Physical exhibits are referred to by trial exhibit number. Petitioner has requested the entire record be transmitted to this Court.

ing to the Task Force recommendations, drugs for step 2 should not be used unless step 1 treatment would not work. Because of its dangerous side effects, the Task Force classified Apresazide as a "step 3" drug, which should not be used unless "first step" and "second step" drugs were ineffective [R. 1289, 1294]. To overcome the Task Force recommendations, Ciba decided to falsely promote Apresazide as "second step" therapy because Ciba did not want Apresazide "to end up as a third step in the therapy sequence . . . because most patients just don't get to a step 3 situation" [R. 1422; DX 102]. Ciba instructed its salesmen how to respond "in the unlikely event" they were questioned about their "second step" promotion [R. 166-167, 1289, 1419, 1442]. Ciba also deliberately violated the generic name labelling requirements of the Food, Drug and Cosmetic laws by not selecting and prominently printing a useful generic name on its promotional materials as required by the Food and Drug laws.[4]

In 1976, Bolar decided to market a generic version of Apresazide and chose to use standardized capsule appearance for reasons of public safety [R. 610-615]. Bolar's application to the Food and Drug Administration for approval of its generic product in the pink/white and blue/white capsules by which the public recognized and identified the drug was approved by the FDA on March 4, 1982. In contrast to

[4] This illegal conduct is remarkable because it was Ciba's own deceptive advertising of Singoserp, another of its antihypertensive drugs, and the failure of its advertising agency to display generic drug names, which resulted in 1962 Amendments to the Food and Drug laws, 21 U.S.C. §§ 352(e), (n) prohibiting such deceptive drug advertising and requiring selection and prominent display of a generic name [R. 952, 965].

the adulterated drug marketed by Ciba, Bolar's generic drug is of the highest quality [R. 432-33]. Before being restrained by the trial court, Bolar marketed its generic product to government agencies, wholesalers and distributors, in distinctive containers with a prominent yellow label cautioning pharmacists to substitute only where permitted by law and only after informing the patient of the substitution [PX 16-17]. Bolar's generic capsules themselves each had Bolar's logo and its National Drug Control Identification Number prominently imprinted on them twice so that Bolar could be readily identified as the source of its product [PX 16-17].

2. The Evidentiary Proceedings

In support of its case, Ciba called Henry Kirsch, its sales director for Apresazide, who admitted that all of Ciba's promotion was directed to physicians and pharmacists, and not to patients [R. 14-19, 93]. Kirsch was unable to distinguish Apresazide capsules from the earlier Minipress capsules and from other earlier capsules also identical in appearance [R. 347-348]. Kirsch admitted that patients associate the capsule colors with the medication itself and do not associate the capsule colors with Ciba [R. 81, 87]. Kirsch also admitted that the names of the ingredients of Apresazide were too cumbersome to use as a generic name, that Apresazide is the common descriptive name for Ciba's product, and that physicians commonly refer to the product in suit as Apresazide [R. 73-77].

Ciba's other employee-witness was Dr. Audrey Kriegman, a recent medical school graduate who has never been in private practice [R. 120, 129, 1795]. She admitted that the name Apresazide served as the common name of the

drug itself, and that patients do not associate the capsule colors with Ciba [R. 136, 143, 147].

Bolar called two expert witnesses, Dr. James O'Donnell, a pharmacist, and Dr. Herbert Silberner, a physician. Dr. O'Donnell is Assistant Director of Pharmacy at Rush Medical Institute, a prominent Chicago hospital center, and a member of the Generic Drug Technical Advisory Council of the State of Illinois which is responsible for approval of all generic drugs in the state [R. 312-316]. Dr. Silberner is a New Jersey physician who has specialized in internal medicine since 1948, and who writes a majority of his prescriptions for generic drugs [R. 507].

Both Dr. O'Donnell and Dr. Silberner testified that capsule color is functional in many ways. To the patient, capsule color identifies the medication itself, and also serves to distinguish one medication from another when two or more dosage forms are intermingled [R. 351, 369, 372]. Capsule color is especially helpful to elderly patients in identifying medication and identifying the purpose of the medication and should be the same regardless of manufacturer [R. 510-513]. Capsule color enables a patient to detect a dispensing error by a pharmacist; Dr. O'Donnell testified from personal experience of instances where a prescription that he had erroneously filled with the wrong medication was returned by a patient who noticed the different color of the medication [R. 376].

Dr. O'Donnell and Dr. Silberner also testified that it is common for patients to resist taking a generic equivalent if the generic drug is a different color because the patient thinks it is an entirely different drug [R. 509-514, 581-585].

Dr. O'Donnell serves as a volunteer at the Chicago Poison Control Center, which gives information to health care specialists about the identity of drugs which have been accidentally or intentionally ingested. Here, too, the color of the drug functions as a means of identifying unknown drugs [R. 373-374]. For this reason and others unrelated to the source of the drug, he testified that when in charge of purchasing drugs for major Chicago hospitals he would pay a significant premium for a generic drug having the publicly accustomed color than for one having a different color [R. 364].

Dr. O'Donnell also confirmed the testimony of Mr. Kirsch and Dr. Kriegman that the term "Apresazide" is the common descriptive name of the drug itself, because Ciba did not select and properly promote any other generic name for Apresazide. A tongue twisting list of its ingredients—"Hydralazine Hydrochloride and Hydrochlorothiazide"—is simply too cumbersome for use, and hence everyone must necessarily use Apresazide as the name of the drug itself [R. 353-361].

Dr. Silberner testified that, to the patient, color functions to identify the medicine itself. When Dr. Silberner prescribes a medication, he offers the patient a generic drug. Even though his patients know that he has prescribed a generic drug (and thus are not confused as to source), they will call both the pharmacist and physician to check whether the correct medicine has been dispensed if it has an unaccustomed appearance [R. 509-514]. None of Dr. O'Donnell's or Dr. Silberner's testimony as to the functionality and meaning of drug color was controverted by Ciba in any way.

REASONS FOR GRANTING THE WRIT

A. The Decision Below Conflicts With This Court's Decision In *Inwood* By Applying The Watered Down And Incorrect Reasonable Anticipation Standard To Prohibit Manufacture And Sale Of A Generic Drug Product In The Accustomed Appearance For The Drug

The decision below is in conflict with the principles established in this Court's decision in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) and with the decision of the Second Circuit in that case following remand, *Ives Laboratories, Inc. v. Darby Drug Co.*, No. 80-7314 (July 7, 1982) (App. 58-60), rejecting the "reasonable anticipation" standard for prohibiting generic drug manufacture in the accustomed drug appearance. Based on their anti-generic drug position, the New Jersey federal courts have become a haven for drug companies seeking protection from generic competition after their patents expire. Bolar and other generic drug companies are now repeatedly being sued in New Jersey for sale of generic drugs in their accustomed color. By evading the rationale of the Court's *Inwood* decision, the New Jersey District Court has effectively established a national policy against manufacture and sale of a generic drug in the only appearance by which the public recognizes the drug.

The undisputed facts here are more compelling than in *Inwood*. Although over a million capsules of Bolar's generic product were sold before Bolar was restrained by the lower courts, there was no evidence of any illegal substitution or "passing off" of Bolar's product for Ciba's product. Nevertheless, the lower courts found that Bolar "passed off" its generic drug by applying the "reason-

able anticipation" test rejected by this Court and the Second Circuit in *Inwood*.

Justice White expressed his concerns in *Inwood* that a generic drug manufacturer should not be held vicariously liable merely because it could "reasonably anticipate" some infringement by its customers:

> The mere fact that a generic drug company can anticipate that some illegal substitution will occur to some unspecified extent, and by some unknown pharmacists, should not by itself be a predicate for contributory liability. . . .
>
> Diluting the requirement for establishing a prima facie case of contributory infringement is particularly unjustified in the generic drugs field. Preventing the use of generic drugs in the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other states, of promoting the substitution of generic formulations. (456 U.S. 861, 862) (Justice Marshall concurring)

The majority opinion in *Inwood* addressed this issue by specifically rejecting the "reasonable anticipation" standard:

> JUSTICE WHITE'S concern is based on a comment by the Court of Appeals that the generic manufacturers 'could reasonably anticipate' illegal substitution of their drugs. 638 F.2d at 543. If the Court of Appeals had relied on that statement to define the controlling legal standard, the court indeed would have applied a 'watered down' and incorrect standard. (456 U.S. 854, note 13)

Because the Second Circuit had based its decision only on §32 of the Lanham Act, this Court could not specifically reject the "reasonable anticipation" standard under

§43(a). On remand the Second Circuit affirmed the judgment in favor of the right to manufacture the drug in its accustomed capsule colors under §43(a) without applying the "reasonable anticipation" standard (App. 58-60). There is no suggestion in *Inwood* that the "reasonable anticipation" standard rejected by this Court under §32 of the Lanham Act is a proper standard under Section 43 of the Act. There is no public policy reason to apply one standard for vicarious liability for "passing off" under §32, and a lesser standard for "passing off" under §43(a).

Nor can *Inwood*'s rejection of the "reasonable anticipation" standard be avoided by the lower courts' presumption that Bolar "intended" to "permit" or "facilitate" illegal substitution by unknown retail pharmacists because it manufactured a product in the only appearance by which it is recognized by the consuming public. That is merely another way of stating that Bolar could "reasonably anticipate" passing off. As pointed out by Justice White in his concurring *Inwood* opinion:

> A functional characteristic is "an important ingredient in the commercial success of the product," 601 F.2d, at 643, and, after expiration of a patent, it is no more the property of the originator than the product itself. It makes no more sense to base contributory infringement upon the copying of functional colors than on the petitioners' decision to use the same formulation of the drug, or even to market the generic substitute in the first p ce. To be sure, the very existence of generic drugs "facilitates" illegal substitution. But Ives no longer has a patent for cyclandelate, "and the defendants have a right to reproduce it as nearly as they can." *Saxlehner v. Wagner*, 216 U.S. 375, 380 (1910) (Holmes, J.). Reproduction of a functional attribute is legitimate competitive activity. [*Id.* at 863]

There is no evidence in the record of any "intent" by petitioner to condone or allow any such wrongdoing; as

the district court's opinion makes clear, petitioner's asserted "intent" in this regard is nothing more than the court's application of the "reasonable anticipation" standard rejected by this Court in *Inwood*. This Court held in *Inwood* that generic manufacturers are free to adopt the accustomed drug appearance, despite the "reasonable anticipation" of wrongdoing by others, so long as they do not encourage or condone the wrongdoing. What the lower courts have done here is to ignore the substantive underpinning of *Inwood* in an attempt to distinguish *Inwood* as a "narrow" case involving only the scope of appellate review.

We believe that Section 43(a) does not constrain the freedom of a generic drug manufacturer to adopt the accustomed appearance for a drug any more than Section 32 does, and that this Court would not have upheld that freedom under one section of the Lanham Act only to watch it perish under another. But if the *Inwood* holding is to perish, surely it should do so only after plenary review of the matter by this Court. The decisions below do not address the issue, let alone subject it to the scrutiny that it deserves.

The lower court's finding that Bolar has "passed off" its generic product is based on the faulty premise that Ciba is entitled to the market demand for the drug product itself, and that because Ciba first encouraged doctors to prescribe it, it is unfair competition for Bolar to produce and sell a generic drug at "much lower cost" (App. 9).

This Court has struck down every attempt to use the trademark laws to prevent competition and extend a patent monopoly. *Scott v. Marcalus*, 326 U.S. 249 (1945); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120-122

(1938); *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896). In *Scott v. Marcalus*, the Court held the goodwill of a product (i.e., the demand for a product in its accustomed form) was public property:

> By the force of the patent laws not only is the invention of a patent dedicated to the public upon its expiration, but the public thereby becomes entitled to share in the goodwill which the patentee has built up in the patented article or product through the enjoyment of his patent monopoly [p. 256].

This Court has never permitted monopolists to appropriate the demand and goodwill associated with the product itself as it was known to the public during the term of the monopoly. As the Court stated in its landmark *Kellogg Co. v. National Biscuit Co.* decision:

> Since during the life of the patents "Shredded Wheat" was the general designation of the patented product, there are passed to the public upon the expiration of the patent, not only the right to make the article as it was made during the patent period, but also the right to apply thereto the name by which it had become known.
>
> * * *
>
> Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights *in a form in which the public has become accustomed to see the article* and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind. (emphasis supplied)
>
> * * *
>
> Kellogg Company is undoubtedly sharing in the goodwill of the article known as "Shredded Wheat"; and thus is sharing in a market which was created by the skill and judgment of the plaintiff's predecessor and has been widely extended by vast expend-

> itures in advertising persistently made. But that is not unfair. Sharing in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested. [305 U.S. 111, 118-122]

The so-called "patent clauses" of the Lanham Act, 15 U.S.C. §§1064(c), 1065(4), were passed by Congress specifically to codify the *Scott*, *Kellogg*, and *Singer* cases, to subordinate the trademark law to patent law, and to protect small drug companies such as Bolar from assertions of trademark law as a legal device to perpetuate a monopoly. See Abraham S. Greenberg, *"Patent" Clauses of the Lanham Act*, 38 Trademark Reporter, pp. 3-47, 19 (1948).

This Court should strike down the use of the "reasonable anticipation" standard to prevent competition and perpetuate drug monopolies.

B. The Decision Below Conflicts With The Decisions Of This Court And The Second Circuit In *Inwood* As To The Standards For "Functionality" Of Drug Color

In *Inwood*, this Court reaffirmed the general test for functionality of a product feature.

> In general terms, a product feature is functional if it is essential to the use or purpose of the article or it affects the cost or quality of the article. See *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 238 (1964); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 122 (1938) [456 U.S. 844, 850]

The evidence is uncontradicted that purchasers such as hospitals (where there is no possibility whatsoever of illegal substitution) will pay a substantial premium to have the generic drug in its accustomed appearance, *irrespective of source*, purely because of the desire to have

the generic drug in the only form by which it has been recognized and identified by patients and to minimize staff training and dispensing error[5] [R. 364-365]. This price premium is substantial, approximating Ciba's entire cost of manufacture of its product [R. 1455; DX 111]. Moreover, the District Court specifically found that the accustomed appearance of the drug makes it "more saleable, because it makes it easier for both the doctor and the pharmacist to substitute the generic drug" (App. 9). The District Court also found that patients will "accept the generic drug more readily" if it has the accustomed appearance by which it is identified and "may resist such substitution, if it does not"[6] [App. 9]. It is also undisputed that Bolar's customers, which include Government agencies, wholesalers and distributors, prefer the product in the accustomed form [R. 364, 218-219, 1589].

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[5] Other circuits in addition to the Second Circuit recognize as "functional" any feature which has value, apart from source identification, which is important to the commercial success of the product. *West Point Manufacturing Co. v. Detroit Stamping Co.*, 222 F.2d 581 (6th Cir. 1955); *Pagliero v. Wallace China Co.*, 198 F.2d 339 (9th Cir. 1952). See also *Vibrant Sales, Inc. v. New Body Boutique, Inc.*, 652 F.2d 299 (2nd Cir. 1981); *Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569 (2nd Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); *American Safety Table Company v. Schreiber*, 269 F.2d 255 (2d Cir. 1959); *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F.Supp. 980 (D. Mass. 1946), *aff'd* 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947).

[6] The District Court Opinion was largely copied verbatim from Ciba's post-trial submissions, and is thus "loaded down with argumentative overdetailed partisan matter . . . of doubtful validity or even wholly without support in the record" *Roberts v. Ross*, 344 F.2d 747, 751-752 (3rd Cir. 1965). However, these findings as to increased "saleability" were written by the Court and, presumably, more accurately reveal the Court's reasoning.

As pointed out in *Famolare, Inc. v. Melville Corp.*, 472 F. Supp. 738 (D. Hawaii, 1979), *aff'd* 652 F.2d 62 (9th Cir. 1981):

> A feature which gives the consumer a substantial reason for purchasing the product, as opposed merely to distinguishing it from other products, is functional.
>
> * * *
>
> Free competition would be impeded if a manufacturer could gain a perpetual monopoly on the reproduction of a feature which contributes directly to the sale of the underlying product. [*Id.* at 743]

The record and the Court's own findings confirm a commercial cost premium, "saleability" and preference for the accustomed drug appearance, *irrespective of source*, because it is the accustomed and only known identification of the drug itself. The accustomed appearance "affects the cost of the drug" and is accordingly functional under the general *Inwood* test. To give a former patent monopolist an undeserved price advantage approximating the cost of manufacture is contrary to the purpose and policies of the trademark, patent and antitrust laws.

In addition to the general test for functionality, this Court affirmed in *Inwood* specific tests of functionality for drug product appearance established by the trial court:

> . . . that the blue and blue-red colors were functional to patients as well as to doctors and hospitals: many elderly patients associate color with therapeutic effect: some patients co-mingle medications in a container and rely on color to differentiate one from another: colors are of some, if limited, help in identifying drugs in emergency situations: and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. [456 U.S. 844 at 823]

The record in this case clearly establishes without contradiction each of these elements of functionality, and more. Capsule colors of Apresazide are functional to patients as well as to doctors, pharmacists and hospitals [R. 81-82, 351, 372, 374-376, 419-420, 424-425, 510-512, 830-839, 1829, 1832;—DX 25, DX 26]. Patients associate color with therapeutic effect and use color to identify the medication itself and its purpose [R. 351-369, 372, 376, 510-511]. Patients co-mingle different medications in a container and rely on color to distinguish one from another [R. 423-425, 510-512; DX 28, DX 29]. Drug appearance functions to distinguish different dosages of a medication, serves as a means for drug identification in emergency situations, facilitates doctor-patient communication and helps avoid confusion in drug dispensing [R. 374-376]. Functionality of drug appearance prevents prescription error and patient harm or death [R. 375-376].

The lower courts specifically rejected these tests and refused to consider the record evidence which fully supports functionality under the tests [R. 697]. For the *Inwood* tests that color may be associated with therapeutic effect and used by patients to distinguish co-mingled medication, the District Court presumed that "constancy" of accustomed drug appearance "will *permit* the patient to identify it with a single source" [App. 38]. This, despite the lack of any advertising to patients.

The District Court rejected the *Inwood* tests "that uniform color *helps* to avoid confusion on the part of those responsible for dispensing drugs", and that "colors are *some, if limited help* in identifying drugs in emergency situations" [456 U.S. 844 at 853]. It substituted its own presumption of law that a drug is functional if a "physician or a pharmacist would prescribe a drug based upon its appearance *only*" and that it must be a dangerous drug

"likely to engender . . . emergency room visits" or "overdose" [App. 37]. This was despite the fact that Apresazide is sufficiently more dangerous than the drug involved in *Inwood*, that the FDA requires a "box warning" for Apresazide [R. 1916-1917; DX 12A—1982 Physicians' Desk Reference]. The lower courts also ignored Dr. O'Donnell's testimony about dangerous prescription errors which are and have been detected by drug appearance alone [R. 375-376]. They also ignored the position of the 55,000 member American Pharmaceutical Association, which is that if standardized drug appearance is prohibited, "the possibility of drug overdose is increased . . . [and] the problem of drug identification in emergency situations, such as accidental poisoning is exacerbated" [R. 831-32].

The apparent basis for the District Court's refusal to adopt the standards for functionality approved by this Court in *Inwood* is its conclusion that color is not functional because patients who identify a drug by its color may be persuaded by doctors and pharmacists that the same drug may have a different color.[7] The District Court reasoned that Bolar therefore must use different colors to avoid any possibility of confusion (App. 22). The District Court's reasoning is in conflict with the holding of this Court in *Kellogg Co. v. National Biscuit* that a competitor is not required to adopt a product appearance different from the accustomed form:

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[7] The Court found that when "a patient already on a brand name product is then dispensed a different-looking generic equivalent . . . the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed." (R. 698). Because the physician tells the patient a generic drug is being dispensed (and indeed, the patient can see this on the prescription itself), this finding *is conclusive proof that accustomed drug appearance identifies the drug product*, not source, defeating the

(Footnote continued on following page)

> It is urged that all possibility of deception or confusion would be removed if Kellogg Company should refrain from using the name "Shredded Wheat" and adopt some form other than that pillow-shape. But the name and form are integral parts of the goodwill of the article. To share fully in the goodwill, it must use the name and the pillow-shape. And in the goodwill Kellogg Company is as free to share as the plaintiff. Compare *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526, 528, 530.

Id. at 121. To share fully in the goodwill of the drug product itself, generic drug companies must be permitted to use the publicly accustomed appearance of the drug.

C. The Decision Below Conflicts With The Decisions Of This Court And The Second Circuit In *Inwood* As To The Standards For Establishing "Secondary Meaning" Of Drug Color

The lower courts failed to follow the long established test for secondary meaning reaffirmed by this Court and the Second Circuit on remand in *Inwood*:

> To establish secondary meaning, a manufacturer must show that in the minds of the public, the *primary significance* of a product feature or term is to

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[7] *continued*

District Court's finding of "secondary meaning". The appearance identifies the drug product because it is the only visual indication by which the drug may be recognized and identified, and has nothing to do with source. It is the accustomed appearance of the product acquired during the patent monopoly which now identifies the drug to the public, and another appearance does not serve this function. Subjecting doctors and pharmacists to patient inquiries and complaints merely because they prescribe a generic drug creates a barrier to competition, and grants Ciba an undeserved price advantage based on factors unrelated to Ciba as a source, including considerations of safety, patient anxiety and ignorance.

> identify the source of the product rather than the product itself. See *Kellogg Co. v. National Biscuit Co., supra*, at 118. (emphasis added) [456 U.S. 844 at p. 851]

There is no evidence of record that either capsule appearance or the name Apresazide signifies the source of the drug product in suit, rather than the drug itself. On the contrary, all of the witnesses testified that capsule appearance signifies the drug. (see footnote 7, *supra*)

Dr. Silberner testified that patients associate size, shape and color with a certain medicine used for a certain purpose, and that many patients cannot remember the names of their drugs [R. 510-513]. The 55,000 member American Pharmaceutical Association officially recognizes that "patients associate drug identity with drug product appearance" [R. 838]. Dr. O'Donnell testified that "patients associate color of medication with what they are taking it for" [R. 372].

Ciba's own marketing director Kirsch testified that patients associate color with the name and identity of the drug itself rather than the source of the drug [R. 80-81].

Dr. Kriegman, Ciba's other principal witness, confirmed that patients don't associate capsule color with plaintiff as a source [R. 142-143].

Nor can any association of capsule color with the drug name "Apresazide" evidence "secondary meaning". Kirsch testified that "Apresazide" is the common descriptive name of the drug, and that "generic Apresazide" or "Bolar's Apresazide" is the most natural way of referring to Bolar's product in suit [R. 73-74].

Dr. O'Donnell testified that "Apresazide" is necessarily the common descriptive name for the drug because there

is no other useful generic name, and that it is the policy of the Official U.S. Adpoted Names Commission that a combination drug such as Apresazide having multiple ingredients should have a separate generic name [R. 355-361].

Ciba has encouraged physicians to write only the word "Apresazide" on prescriptions, so that this is the only name patients will ever see [R. 1513]. Accordingly, the public *necessarily* uses "Apresazide" as a common descriptive name for the drug, because it is the *only name* provided by Ciba.

A landmark case on this point was *Bayer v. United Drug*, 272 F. 505 (S.D. N.Y. 1921) in which the famous trademark "Aspirin" was at stake. After the patent expired, Bayer sought to enjoin a competitor from using the term "Aspirin". Judge Learned Hand analyzed the case as follows:

> [A]lthough physicians appear to have used the terms, "Aspirin" or "acetyl salicylic acid" indifferently, it cannot be that such patients as read their prescriptions attributed to "Aspirin" any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue. Nor is there any evidence that such as may have seen both terms identified them as the same drug. I cannot speculate as to how many in fact did so. No packages could possibly have reached the consumer, nor was any advertising addressed to them; their only acquaintance with the word was as the name for a drug in whose curative properties they had got confidence. (272 F. 510).

There is no evidence in the record that the general consuming public has had any acquaintance with the term "Apresazide" or the dosage-coding colors of Apresazide

other than as the name or color of a "drug in whose curative properties they had got confidence".

As discussed by Professor McCarthy in his treatise *Trademarks and Unfair Competition* at page 405:

> The name of a product or service itself—what it is—is the very antithesis of a mark. In short, a generic name of a product can never function as a trademark to indicate origin. The terms "generic" and "trademark" are mutually exclusive. As noted previously, the function of a mark is to identify and distinguish the goods or services of one seller from those sold by all others. A mark answers the buyer's question "Who are you? Where do you come from?" But the name of the product answers the question "What are you?" (footnotes omitted)

Ciba selected the name Apresazide to answer the question "What are you" (i.e., "what the product is"). Any association of capsule color with "what the product is" cannot signify Ciba as a source.[8]

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[8] The Court's finding that "Apresazide" is not a generic name simply because Bolar has refrained from using the word to avoid litigation is based on an improper legal standard [R. 704, 718]. In the famous "Cellophane case", defendant's non-use of the trademark "cellophane" did not prevent the word from being generic:

> "In the case at bar the defendant has never used either the words "cellophane" or "DuPont cellophane" with or without the oval, on its goods. It has merely filled orders for cellophane with its own product" [*DuPont Cellophane Company, Inc. v. Waxed Products Co., Inc.*, 30 U.S.P.Q. 332-3329 (1948)]."

Moreover, the Court's finding that Hydralazine Hydrochloride/Hydrochlorothiazide is a generic name does not counter the evidence that Apresazide is also generic and is used generically. A product may have multiple generic names, each of which describes the product in suit. As pointed out by Professor McCarthy in his treatise (*supra*) at page 408:

(Footnote continued on following page)

Where there is no other name for a product, or the only synonym for identifying the specific product is a cumbersome technical term not generally known to purchasers, it is inadequate for use by competitors and will not prevent the mark from being generic. *Anti-Monopoly, Inc. v. General Mills Fun Group, Inc.*, 684 F.2d 1316 (9th Cir. 1982), *cert. den.*, ... U.S. ..... (1983) ("Monopoly"); *DuPont Cellophane Co. v. Waxed Prods. Co.*, 85 F.2d 75 (2nd Cir. 1936) ("Cellophane"); *Haughton Elevator Co. v. Seeberger*, (Com. of Pat. 1950), 85 U.S.P.Q. 80 ("Escalator"); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938) ("Shredded Wheat"); *King Seeley Thermos Co. v. Aladdin Industries, Inc.*, 321 F.2d 577 (2nd Cir. 1963) ("Thermos").

"Apresazide" is the common descriptive name of a prescription drug, and any association of capsule appearance with the name Apresazide, which is the common name of the drug and which is the only name available to patients, cannot show "secondary meaning", 15 U.S.C. §§1064(c), 1065(4).

Common pink/white and blue/white capsules cannot uniquely signify Ciba as a source because they are common in the channels of drug commerce. There is

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[8] *continued*

> There is usually no one, single and exclusive generic name for a product. Any product may have many generic designations. Any one of those is incapable of trademark significance.
>
> * * *
>
> Even if there exists another suitable word to call the product, the public may pick as a generic name the word claimed as a mark by the seller. However, most names become generic because the public is not given any other word to apply to an unfamiliar product. The term which the seller claims is the generic designation other than his "mark", may be so unwieldly and complicated that the public will not accept it. (citations omitted)

nothing special or unique about the colored capsules in suit. There are many drug products of different drug companies having the same or similar appearance as Apresazide [DX 13A, 13B, 14-22; R. 82, 322-323, 800, 802]. Physicians complain that Apresazide capsules look like the earlier-marketed Indocin [R. 1278—DX 65], and Ciba has received complaints that Apresazide looks like the earlier Minipress[9] [R. 782, 786—DX 8, 9]. These complaints confirm the use of capsule color as an identifier of medication and have nothing to do with identification of Ciba as a source.

The identity or confusing similarity of Ciba's capsule colors with those of Minipress, Indocin and many other drugs prevents acquisition of "secondary meaning". By the time Ciba introduced Apresazide, Minipress had been in the marketplace for several months. Both sales and promotional expenditures for Pfizer's Minipress greatly exceed those of Apresazide [R. 93, 1030, 1056—DX 38, 44].

It is hornbook law that a valid trade dress cannot designate multiple sources, and it is accordingly impossible for Ciba to develop any exclusive trade dress rights or secondary meaning in colors of prior products in the same channel of commerce:

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[9] Ciba's own Sales Director Kirsch, when presented with blue/white and pink/white capsules of the earlier marketed Minipress and Dynapen (an antibiotic) confused them with Apresazide and testified that physicians and pharmacists would associate them with Apresazide [DX 6; R. 83-84, 347-348]. Ciba assured the FDA that using the same colors as Minipress was not a problem because the capsule markings were sufficient to prevent confusion as to drug identity [R. 782, 786—DX 8, DX 9]. Here, however, it argues precisely the opposite; that Bolar's markings will not identify Bolar as a source.

> [I]t is vital to the existence of a trade-mark that it should be used by only one concern. A trade-mark cannot serve two masters; it cannot identify two sources at the same time and remain a trademark. [Nims, Unfair Competition and Trademarks, Fourth Edition, Vol. Two, p. 1289].

The lower court's grant of rights in standard capsule colors which were already on the market in the earlier Pfizer product and other drug products used by patients is improper. Such capsule color cannot indicate a "single product from a single source" because it is used for multiple products from multiple sources in the same channel of commerce, any of which might be prescribed for patients taking multiple medications, simultaneously or at different points in time.

The decision below conflicts with the District Court decision in *Inwood*, affirmed by this Court, that mere "copying" of the accustomed appearance of a drug by a generic drug manufacturer, and prior sales of the drug by the former patient holder, do not establish "secondary meaning."

D. The Lower Courts Improperly Based A Nationwide Injunction On New Jersey State Law To Evade This Court's *Inwood* Decision

Bolar manufactured its generic product in New York, having a physical appearance properly approved under Federal law by the United States Food and Drug Administration. Bolar is not located in New Jersey and intentionally avoided all sales of its product into New Jersey. The lower court decisions thus constitute a nationwide enforcement of New Jersey state law in an area preempted by Federal Statute. The decision below applies New Jersey state law, without subject matter jurisdic-

tion over a New York corporation lawfully manufacturing in its own state, to interfere with the generic drug substitution laws of the other states.

The approval of Bolar's product by the U.S. Food and Drug Administration constitutes a Federal Agency determination that Bolar's product is *not* a drug "falsely purporting . . . to be the product of . . . [any] other drug manufacturer . . ." [21 U.S.C. §321(g)(2)]. This determination was made pursuant to specific FDA policy "routinely to approve new drug applications for drug products that duplicate the color, size and shape" of the original product, but not to require such duplication [R. 1586]. Where federal law comprehensively regulates an area of national concern such as the manufacturing of food or drug products, additional regulation by the states of such manufacture and sale, particularly outside their borders, is preempted.[10] *Cloverleaf Butter Co. v. Patterson*, 315 U.S. 148 (1942); see also, *McDermott v. Wisconsin*, 228 U.S 115 (1913); *Campbell v. Hussey*, 368 U.S. 297, 301 (1961); *Pennsylvania R.R. v. The Public Service Commission*, 250 U.S. 566, 568-69 (1919); *Local 174, Teamsters Union v. Lucas Flour Co.*, 369 U.S. 95, 103 (1962); *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 242 (1959).

It is the policy of the various state substitution laws to promote generic substitution. The Attorney General for the State of New York, where Bolar manufactures its product, strongly favored generic drugs in the accustomed

[10] In addition, New Jersey is precluded by the overriding policy of the patent laws from preventing Bolar from copying and selling the previously patented product in its accustomed form. *Compco Corp. v. Day Brite Lighting, Inc.*, 376 U.S. 238 (1964); *Sears, Roebuck & Co. v. Stiffel Company*, 376 U.S. 225 (1964).

drug color in his *Amicus* brief in *Inwood*. That the various state substitution laws are frustrated by preventing uniformly colored generic products is pointed out by Justice White's concurring opinion in the *Inwood* case:

> Preventing the use of generic drugs of the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other states, of promoting the substitution of generic formulations. [456 U.S. 844 at 861]

The lower court's injunction frustrates the various state substitution laws, and is an improper regulation of interstate commerce prohibited by the Constitution.

E. The Decision Below Granting Exclusive Trade Rights From Illegal Drug Sales And Promotion Is In Conflict With The Decisions Of This Court And The Other Circuits

The decisions below establish a dangerous precedent by permitting the acquisition of exclusive trade rights solely from illegal drug marketing activities [R. 469-480]. As earlier discussed, sales of Apresazide relied on by the lower courts to prove secondary meaning included sales of an adulterated drug, and all of Ciba's promotion evidence, relied on by the lower courts as proof of "secondary meaning", was illegally designed to mislead physicians into believing that Apresazide is recommended as "second step" therapy by the prestigious National High Blood Pressure Education Program Task Force. 21 U.S.C. §§351, 352(e),(n).

To prevent "profit when generic names cannot be remembered" [R. 952; DX 31], and to insure that useful generic names for drugs are in the public domain, Congress required that *all prescription drug advertisements*

have a generic name printed in type half as large as any corresponding brand name [21 U.S.C. §§ 352(e),(n); R. 870-72]. Ciba has also intentionally violated the generic name promotion law in all of its advertisements. The penalty for false advertising and for failure to comply with the generic name labelling requirement is that Ciba's Apresazide is "deemed misbranded" and is not legally in commerce. 15 U.S.C. §§331, 352. *United States v. Urbuteit*, 335 U.S. 355 (1948).

This Court has never permitted acquisition and enforcement of exclusive rights in a drug based on misrepresentation to the public of the nature of the product. *Morton Salt Co. v. Suppinger*, 314 U.S. 488 (1942); *Worden v. California Fig Syrup Co.*, 187 U.S. 516 (1902); *Manhattan Medicine Co. v. Wood*, 108 U.S. 218 (1882). Misbranded and adulterated drugs such as Ciba's Apresazide are not legally "in commerce" for purposes of the trademark laws because tradermark rights, either at common law or under the Lanham Act, are acquired and maintained only by lawful use, and the grant of exclusive trade rights cannot be based on such illegal use. *Strey v. Devine's, Inc.*, 217 F.2d 187 (7th Cir., 1954); *Cameo, Inc. v. Plough, Inc.*, 185 U.S.P.Q. 228 (N.D. Ohio 1975); *In re Stellar International Inc.*, 59 U.S.P.Q. 48 (TTAB 1968); *Clairol Incorporated v. Holland Hall Products, Inc.*, 165 U.S.P.Q. 214 (TTAB 1970); *In re Taylor*, 133 U.S.P.Q. 490 (TTAB 1962).

The reliance by the courts below on illegal marketing and drug sales establishes a dangerous precedent which should be reviewed by this Court.

CONCLUSION

It is respectfully submitted that a Writ of Certiorari should issue to review the decisions below against manufacture of generic drugs in publicly accustomed form. The decisions adversely affect competition in the drug industry, and transcend the interests of the litigants.

Respectfully submitted,

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